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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/731,519	12/06/2000	R. David Rines	9558	
7	590 01/21/20	5	EXAMINER	
Rines and Rines 81 North State Street			RIMELL, SAMUEL G	
Concord, NH			ART UNIT	PAPER NUMBER
			2165	
			DATE MAILED: 01/21/200	5

Please find below and/or attached an Office communication concerning this application or proceeding.

	_	Application No.	Applicant(s)		
Office Action Summary		09/731,519	RINES, R. DAVID		
		Examiner	Art Unit		
		Sam Rimell	2165		
Period fo	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply				
THE - External after - If the - If NC - Failu	ORTENED STATUTORY PERIOD FOR REPL' MAILING DATE OF THIS COMMUNICATION. nsions of time may be available under the provisions of 37 CFR 1.1 SIX (6) MONTHS from the mailing date of this communication. period for reply specified above is less than thirty (30) days, a reply period for reply is specified above, the maximum statutory period or re to reply within the set or extended period for reply will, by statute reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be time y within the statutory minimum of thirty (30) days will apply and will expire SIX (6) MONTHS from the cause the application to become ABANDONE.	nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133).		
Status					
1)	Responsive to communication(s) filed on				
2a)⊠	This action is <b>FINAL</b> . 2b) This	action is non-final.			
3)	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is				
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.				
Dispositi	on of Claims				
4)🖂	Claim(s) 1-22 is/are pending in the application.				
	4a) Of the above claim(s) is/are withdrawn from consideration.				
	5) Claim(s) is/are allowed.				
6)⊠	☑ Claim(s) <u>1-22</u> is/are rejected.				
	Claim(s) is/are objected to.				
8)[	Claim(s) are subject to restriction and/o	r election requirement.			
Application Papers					
9)☐ The specification is objected to by the Examiner.					
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).					
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority u	ınder 35 U.S.C. § 119				
_	Acknowledgment is made of a claim for foreign All b) Some * c) None of:  1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the prior	s have been received. s have been received in Application rity documents have been receive	on No		
* S	application from the International Bureau see the attached detailed Office action for a list	* **	SAM RIMELL		
			PRIMARY EXAMINER		
Attachment	• •				
	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948)	4) Linterview Summary ( Paper No(s)/Mail Da			
3) 🔲 Inform	nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) r No(s)/Mail Date		atent Application (PTO-152)		

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1-2, 4-12 and 14-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Bassett, Jr. et al. (U.S. Patent 6,453,241).

Claim 1: FIG. 6 discloses the generation of an image derived from the analysis of genes or proteins. Col. 5, lines 1-13 describes the usage of a scanning device which scans the image. The image is then stored in a database (106). The image can subsequently be retrieved for various forms of analysis (col. 11, lines 35-38). The image patterns are standardized in the sense that they are all two dimensional and in color. The individual spot images are of standard size (FIG. 6) and follow a standard protocol for contrasting the spots (the spot is green or red, col. 4, lines 24-29). Col. 20, lines 22-39 outlines the steps of taking the individual spots and comparing them by the usage of data viewers.

Claim 2: FIG. 6 discloses the generation of an image derived from the analysis of genes or proteins. The image is a pattern of spots. The pattern is gene specific (see FIG. 6 where the pattern is specific to a particular gene name). The image may be derived from a polymerase chain reaction that involves an electrophoresis separation, typically occurring a gel (col. 7, lines 61-65). A scanning device scans the image and stores the scan in a database (106). As seen in FIG. 1, multiple users (108, 116) can input the spot patterns into the database. Multiple users can

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retrieve the data from the database as well (col. 19, lines 16-17). The individual spot images are of standard size (FIG. 6) and follow a standard protocol for contrasting the spots (the spot is green or red, col. 4, lines 24-39). Col. 20, lines 22-39 outline the steps of taking individual spots and comparing them by the usage of data viewers.

Claim 4: As seen in FIG. 1, all communications with the database (106) are made by entities (108, 116) that are external in relation to the database (106).

<u>Claim 5:</u> Communications may be achieved over the Internet (112 in FIG. 1).

Claims 6: Any equipment used in a laboratory to achieve the electrophoresis described at col. 7, lines 61-66 reads as a customized kit for identifying genes. Also note applicant's statement on page 7, line 10 of the specification, where applicant states: "Apart from the resulting spot pattern images displayed on the gel, the details of such PCR-electrophoresis operations form no part of the novelty of the present invention."

<u>Claim 7:</u> Electrophoresis equipment is customized for identifying genes. Without any description as to how the kit is customized, the claim reads on any electrophoresis equipment. Also not applicant's statement on page 7, line 10, of the specification.

<u>Claim 8:</u> Any electrophoresis equipment can be used for identifying unknown genes.

<u>Claim 9:</u> The image comparison permitted by the system of Bassett, Jr. et al. can assist in the identification of mutations (col. 42, lines 22-24).

<u>Claim 10:</u> The system of Bassett, Jr. et al. permits the evaluation of specific drug candidates on cells, thus aiding in identifying target cells affected by these drugs (col. 24, lines 60-62).

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Claim 11: Col. 19, lines 13-21 describe the access of the database (or databases) by external researchers. Since the system is available over the Internet (112 in FIG. 1), the information in the databases has a global reach.

Claim 12: See remarks for claim 1.

Claim 14: See remarks for claim 4.

Claim 15: See remarks for claim 5.

Claim 16: See remarks for claims 2 and 6.

Claim 17: Col. 19, lines 13-21 describe the presence of other databases maintained by other research entities, which read as "protein databases", since they also contain the same biological response data as the database (106). The "biological response software" (304) reads as the "protein modeling software" since the biological response, such as the pattern of dots in FIG. 2, provides a visualization model of gene based or protein based materials.

<u>Claims 18-20:</u> Col. 19, lines 13-21 describe other genomic references in the form of other research entities, "biological response software" that reads as "protein modeling software" and other databases (col. 19, line 14 in particular).

<u>Claims 21-22:</u> Each of the images are the same two dimensional color images. The images are thus standardized (they all have the same 2-D color format) and the standard dictates the size (two dimensions) and contrast (full color images).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

<sup>(</sup>a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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Claims 3 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bassett, Jr. et al. ('241).

Claims 3 and 13 differ from the claims in that it does not specifically disclose multiplex polymerase chain reaction by two dimensional scanning. Basset, Jr. et al. only disclose polymerase chain reaction in general terms.

However, multiplex polymerase chain reaction by two dimensional scanning is well known in the art by applicant's admission in the disclosure (page 1, second paragraph of specification).

Bassett. Jr. et al. also states that other systems are within the spirit and scope of the invention (col. 5, lines 30-35).

It would therefore have been obvious to one of ordinary skill in the art to modify Bassett, Jr. et al. to obtain data by multiplex polymerase chain reaction by two dimensional scanning as a choice of design well known in the art by applicant's own admission and applicable to Bassett Jr. et al. as another system for generating biological responses (col. 5, lines 30-35 of Bassett Jr. et al.).

## **Remarks**

Applicant's arguments have been considered.

Applicant's arguments are primarily addressed to the amendments presented within the independent claims 1,2, 12 and 16. These amendments call for the spot images themselves to have standard size and contrast and for optical comparison of the spot images. However, examiner maintains that Bassett, Jr. et al. has these recited features. FIG. 6 illustrates that the individual spots are of a uniform size. Col. 20, lines 22-39 outline the steps of taking the

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individual spot images and performing optical comparisons of the images by the usage of data viewers.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Sam Rimell at telephone number (571) 272-4084.

> Sam Rimell **Primary Examiner** Art Unit 2175